EXHIBIT 230

Amide
PHARMACEUTICAL, INC.

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February 28, 2006

Douglas I. Ellsworth, Director
New Jersey District
United States Food and Drug Administration
10 Waterview Boulevard, 3rd Floor
Parsippany, New Jersey 07054

Dear Mr. Ellsworth,

We respectfully submit this letter and its enclosures in response to form FDA 483, Inspectional Observations, presented to Mr. Divya C. Patel, President of Amide Pharmaceutical, Inc. FDA Consumer Safety Officer Ms. Tara R. Gooen submitted the observation to Amide on February 8, 2006.

Before addressing the observation, Amide wishes to express its appreciation to the Consumer Safety Officer, Ms. Gooen, for her courtesy and cooperation during the inspection.

The following responses relate to Observations 1 through 5 that concern the Postmarketing Drug Experiences Reporting System:

Amide has contacted the Office of Drug Safety and based on their recommendation, Amide will review and submit new, or amended reports to, previously submitted alert reports from 1999 to 2005. Amide shall send the summarized periodic reports for each product covering the time period of first anniversary date to March 31, 2006. From April 1, 2006 forward, Amide shall follow the FDA guidelines on Periodic report submission based on recommendations from the Office of Drug Safety.

Amide is also preparing a SOP for Triage of Case Information and Management of Adverse drug Reaction Reports in which the following will be implemented:

1. All ADEs received by Amide will be classified into serious, unexpected, or non-serious and expected.
2. All 3500A forms will be checked for accuracy and completeness by a second person.
3. All follow-up will be done for ADEs where required.
4. Literature reviews will be performed and any ADE identified will be reported appropriately.
5. All ADE 3500A forms will be faxed to FDA.
6. For all ANDA products, periodic reports will be submitted to FDA's Office of Drug Safety.

Specific response to each item is listed below:

Observation 1

Adverse drug experience information has not been reported to FDA.

Specifically, the following adverse drug experiences or information regarding serious, unexpected adverse drug experiences were not submitted to FDA.

(a) Unsubmitted serious, unexpected 15-day alert experiences, where Amide (the application holder or responsible party) did not submit to FDA, e.g.:

MRN	*Date Rcvd by Mfr*	*Suspect Amide Drug*	*Adverse Experiences*
[redacted]			
02-006	5/3/2002	Digitek (digoxin) Tablets	Congestive cardiac failure, Cataract extraction, Visual disturbance NOS, Fatigue, Weakness, Anorexia, Weight Decreased
03-017	3/28/2003	Digitek (digoxin) Tablets 0.25 mg	Generalized weakness, Atrial fibrillation, feeling of semi-consciousness, Possible digoxin toxicity
[redacted]			

Response: All the above listed cases will be reviewed and submitted as an amended 15 day alert report where required.

(b) Unreported or inaccurate information from serious, unexpected 15-day alert reports, as documented on telephone records or in forwarded case information from a contracted affiliate, e.g.:

MRN	*Date Rcvd by Mfr*	*Suspect Amide Drug*	*Adverse Experiences*
00-015	5/9/2000	Digitek Tablets (digoxin) 0.25mg / ANDA 40-282	Death in 2.5 hours after ingestion of first tablet
• Unreported information: Previous Condition – Diabetic			
01-020	9/7/2001	Digitek (digoxin) 0.125g Tablets / ANDA 40-282	Feet swelling
• Unreported Information: Event reappeared after reintroduction of medication, dehydration, low potassium level, arrhythmia			

[redacted]

Response: The source documents will be reviewed against the final Medwatch report by a health care professional for accuracy and completeness prior to submission. .

(c) Unreported follow-up information from the patient's doctor regarding the following serious, unexpected adverse drug experience:

MRN	*Date Rcvd by Mfr*	*Follow-up Information Date Rcvd by Mfr*	*Suspect Amide Drug*	*Adverse Experiences*	*Follow-up information reported by Physician*
00-015	5/9/2000	7/24/2000	Digitek Tablets (digoxin) 0.25mg	Death in 2.5 hours after ingestion of first tablet	Allergic to codeine, Cause of Death: Arrest

Response: The follow up information for the above case will be reviewed and submitted on follow up MedWatch form. The follow up information will be highlighted to differentiate from the initial information.

Observation 2

Adverse drug experiences that were the subject of post marketing 15-day reports were not investigated.

Specifically, there were no follow-up investigations for the following serious, unexpected experiences:

MRN	*Date Rcvd by Mfr*	*Suspect Amide Drug*	*Adverse Experiences*	*Submitted to FDA*	*Expected Follow-up*
01-020	9/7/2001	Digitek (digoxin) Tablets 0.125mg	Swollen feet	Yes	Determine resolution of experience, as patient's experience had not resolved at the time of reporting.
02-006	5/3/2002	Digitek (digoxin) Tablets	Congestive cardiac failure, Cataract extraction, Visual disturbance NOS, Fatigue, Weakness, Anorexia, Weight decreased	No	Determine resolution of experience, as patient's experiences had not resolved at the time of reporting.
[redacted]					

Response: Amide had sent an inquiry/response to the complaint (ADE). However a follow-up correspondence was not sent to the customer for each of these complaints when additional information requested was not received.

Amide will make reasonable efforts to obtain sufficient information for every case in order to complete a FDA Form 3500A. In the event that the initial information is insufficient, Amide will make the initial contact via two (2) separate phone calls, with at least one (1) phone call to the reporter within two (2) business days. The letter will be sent to the reporter requesting information if the initial contact cannot be made.

Amide is preparing the SOPs for Triage of Case Information and Management of Adverse Drug Reaction Reports

Observation 3

Adverse drug experience information obtained or otherwise received from any source was not reviewed, including information from commercial marketing experience and reports in the scientific literature.

Specifically, incoming adverse drug experiences from spontaneous, clinical trials, and scientific literature are often not reviewed for seriousness and/or expectedness. Any adverse experience which the firm submits to FDA is submitted as a 15-day expedited report.

Additionally, the firm receives published literature on a monthly basis for review, but does not capture serious, unexpected experiences for cases requiring 15-day expedited reports, per Departmental Operating Instructions RA-009, Adverse Drug Experiences (ADE) Reporting to FDA, effective 7/20/2002.

Response: Literature review will be done on a weekly basis using "Reaction Weekly". The process for the Literature report review will follow a similar guideline as that used for serious / unexpected adverse event reporting.

Amide is preparing the SOPs for Triage of Case Information and Management of Adverse Drug Reaction Reports.

Observation 4

Individual ADEs which were not reported to FDA in a post marketing 15-day alert have not been included in a periodic safety report.

Specifically, the firm has never filed a periodic report with FDA. ANDA and NDA approval dates range from 2/28/1997 to 10/24/2005. The firm's procedure, Departmental Operating Instructions RA-009, Adverse Drug Experiences (ADE) Reporting to FDA, effective 7/20/2002, requires the submission of periodic reports. Several adverse experiences remained unreported, e.g.:

MRN	*Date Rcvd by Mfr*	*Suspect Amide Drug / ANDA*	*Adverse Events*	*Seriousness / Expectedness*
03-011	3/17/2003	Digitek Tablets (digoxin) 0.125mg / ANDA 40-282	Unresolved loss of taste	Non-serious / Unexpected
[redacted]				
04-002	1/23/2004	Digitek Tablets (digoxin) 0.125mg / ANDA 40-282	Frequent bowel movements, Fatigue, Lightheadedness, Paleness, Abnormal feeling	Non-serious / Unexpected
04-038	8/6/2004	Digitek Tablets (digoxin) 0.25mg / ANDA 40-282	Appetite decreased, Weight loss, Tiredness, Tremors	Non-serious / Unexpected
[redacted]				
04-042	8/18/2004	Digitek Tablets (digoxin) 0.25mg / ANDA 40-282	Black tooth deposits	Non-serious / Unexpected
04-053	9/20/2004	Digitek Tablets (digoxin) 0.125mg / ANDA 40-282	Nausea, Vomiting, Confusion, Heart block	Non-serious / Expected
[redacted]				Expected

Further, 17 periodic adverse experiences reported by one nurse in September 2000 were not submitted for atrial fibrillation and lack of effect when taking Digitek (digoxin) Tablets. The nurse reported that 20 patients were switched to the innovator brand and his/her adverse experiences resolved within three weeks; only 3 reports were submitted. (I believe this should be in bold-face)

Response: Amide shall send the summarized periodic reports for each product covering the time period of first anniversary date to March 31, 2006. From April 1, 2006 we will follow the FDA guidelines on Periodic Report Submission.

Submits periodic reports to the FDA for each approved ANDA in accordance with the following schedule:

- For the first three (3) years after approval of the ANDA, the periodic report will be submitted quarterly within thirty (30) days of the last day of the reporting quarter, with the beginning of the first quarter starting on the date of approval of the application or the first of the following month, whichever is closer.
- After the first three (3) years of marketing of an approved product, periodic reports will be submitted annually within sixty (60) days of the anniversary date of approval of the application for the product or the first of the following month, whichever is closer.

Observation 5

Written procedures have not been developed for the evaluation and reporting to FDA of post marketing adverse drug experiences.

Specifically:

(a) There is no procedure regarding the initiation of follow-up investigations or serious, unexpected adverse experiences.

(b) There is no procedure to adequately complete the MedWatch Form 3500A in that the firm never completes Adverse Event Terms, Section G8.

(c) There is no procedure for a review of MedWatch Forms to assure the accuracy of information reported to FDA. The firm does not conduct reviews of the cases prior to submission, e.g. the information in the 'Describe event or problem', Section B5, was often incomplete and 'Date received by manufacturer', Section G4, was often inaccurate.

Response: Amide will create comprehensive SOPs for Triage of Case Information and Management of Adverse drug Reaction Reports.

SOPs for Triage of Case Information and Management of Adverse drug Reaction Reports will be prepared and circulated by March 15 and the procedures implemented by April 1, 2006.

Response related to Observations 6 to 8 in regards to Good Manufacturing Practices:

Amide is revising its SOP for Handling of Complaints, Deviations and Investigations to address and review unexplained discrepancy whether or not the batch has been distributed. The SOP's will be completed by March 15 and implemented by April 1, 2006.

Specific response to each item is listed below:

Observation 6

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been thoroughly distributed.

Specifically:

(a) **The firm failed to investigate thirteen consumer complaints for Amidrine Capsule breakages, nine received 2/27/2004 – 7/16/2004 and four received 2/9/2005 – 5/17/2005. Four total complaints were received for lot 3636A1 (2/27/2004, 6/15/2004, 6/29/2004, 5/17/2005). No evaluation of the decision and impact on previous batches was conducted regarding a change form red opaque/white opaque capsule shells to white opaque/white opaque capsule shells. The capsule shells were changed upon advice from the capsule shell manufacturer to prevent breakage.**

Further, although a change control request was approved on 7/27/2004 approving the use of white opaque/white opaque capsules, the firm continued to use red opaque/white opaque capsules in three additional batches (7/29/2004, batch 4360A; 8/6/2004, batch 4397A; 8/9/2004, 4398A) until the supply was exhausted.

Response: There are many factors that may contribute to the observation of "cracked" capsules. We have observed that storage condition and handling (during product shipment) have the strongest influence. In particular, we found a strong correlation between the storage of finished, packaged product and humidity level (even within the specified temperature and humidity range). Product stored at the lower end of the humidity range exhibited a greater tendency to become cracked during product shipment and transportation to customers. Amide contacted the capsule manufacturer to their seek assistance and guidance to resolve this matter. Their recommendation was to alter our capsule color from red/white to white/white. Based upon their recommendation, the product was reformulated. Following this change, we have not received any correspondence or complaints form customers regarding cracked" capsules.
Amide is revising the SOP for Handling of Complaints to investigate any complaints where a trend may be observed.

[redacted]

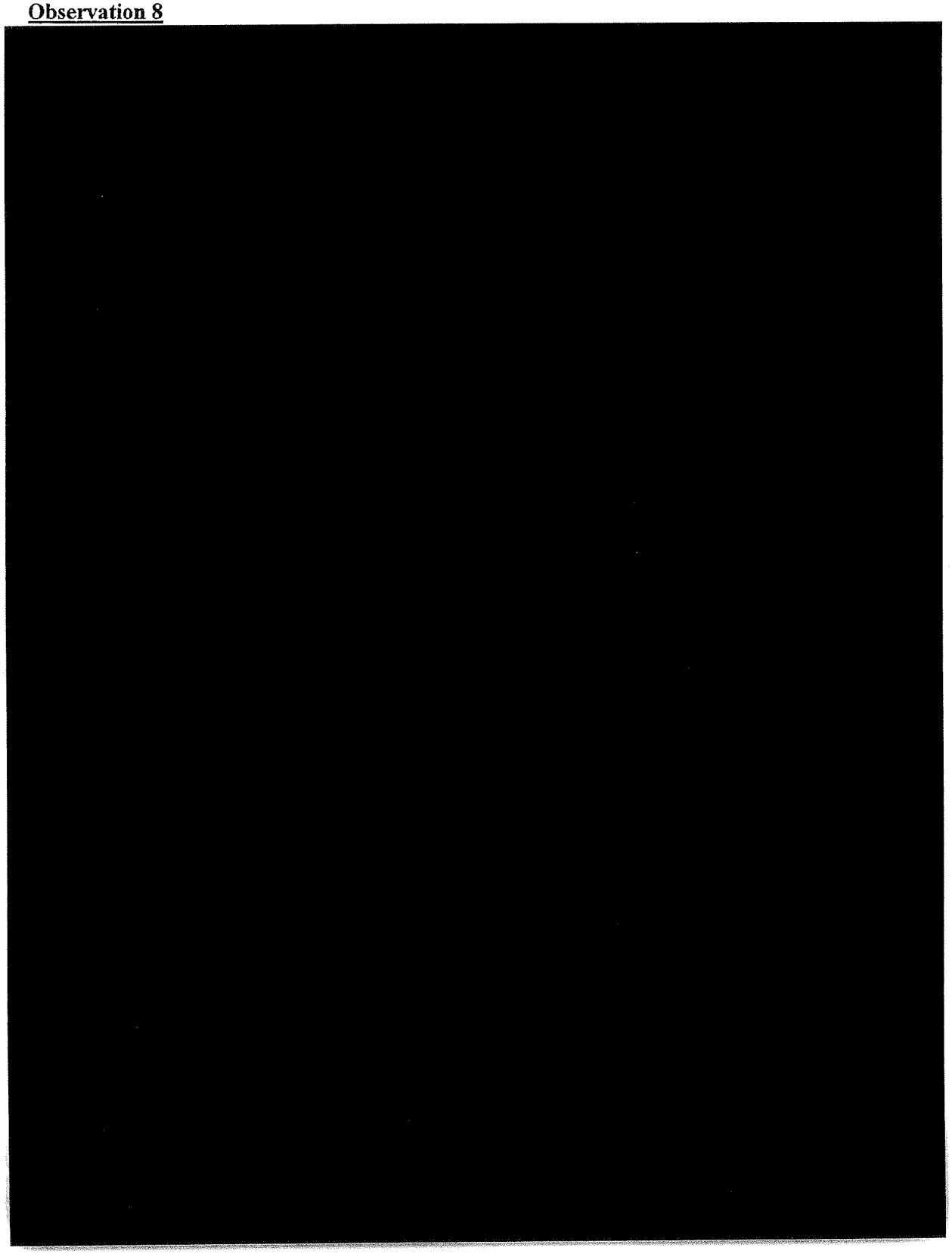
[redacted]

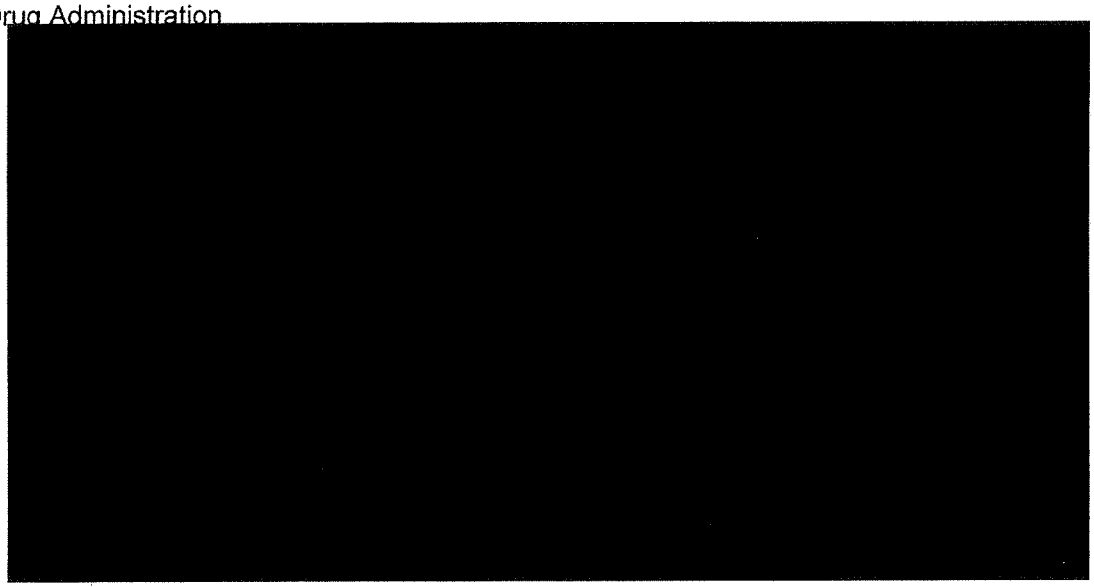
Observation 7

Complaint procedures are deficient in that they do not include provisions that allow for the review and determination of an investigation by the quality control unit.

[redacted]

Observation 8





We have taken the appropriate actions to correct deficiencies and have implemented procedures to preclude their recurrence wherever possible.

We have responded to these Inspectional Observations in a prompt and positive manner, and we commit ourselves to a continuing review of all products and procedures to assure compliance with regulations.

I shall contact you upon issuance and implementation of all the SOPs.

Upon completion of your review, please contact me to discuss any outstanding issues or additional clarifications you may require.

Please direct any written communications regarding this correspondence to me at the above address. If you need to call or fax me, my phone numbers are 973-890-1440 (work), [redacted] (cell) and 973-890-7980 (fax).

Very Truly Yours
AMIDE PHARMACEUTICAL, INC.

Jasmine Shah, M.S., R.Ph.
Vice President Regulatory Affairs and Quality Compliance

Enc. Inspectional Observations and Response.

cc. Ms. Tara Gooen, Consumer Safety Officer
Ms. Sarah DellaFave, Compliance Officer
Mr. Ray Abrahms, Compliance Director
Ms. Carol Krueger, Office of Compliance, CDER